

REMARKS

Claims 37-64 are currently pending in the application. Claims 62-64 are withdrawn from consideration. Claims 37, 39-41, 43-45, 54-57, and 61 are currently amended. Claims 38, 47, and 49-53 are canceled. Claims 65-68 are new. Support for the claim amendments and new claims can be found throughout the specification and claims as originally filed. No new matter is added.

Amendment of the originally filed claims, or cancellation of any claims, should in no way be construed as an acquiescence, narrowing, or surrender of any subject matter. The amendments are being made not only to point out with particularity and to claim the present invention, but also to expedite prosecution of the present application. Applicants reserve the right to prosecute the originally filed claims further, or similar ones, in the instant or subsequently filed patent applications.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 37-61 under 35 U.S.C. § 112, first paragraph for allegedly failing to comply with the written description and enablement requirements. In particular, it is the Examiner's contention that only the isolated antibody, H36.D2.B7 (ATCC HB12255) is adequately described in the disclosure and that the only cancer that the antibody has been shown to effectively treat is a solid tumor.

However, the instant specification specifically describes antibodies other than the H36.D2.B7 antibody represented by SEQ ID NO. 4. For example, the specification specifically describes the chimeric antibody, cH36, and generally describes means to modify the light chain and/or heavy chain variable regions of H36.D2.B7. Based on the same specification, the U.S. Patent and Trademark Office has previously issued claims to "an antibody that binds native human tissue factor to form a complex whereby factor X binding to the complex is inhibited." (See claim 15 of U.S. Patent No. 6,555,319, which is attached hereto as Appendix A).

Moreover, the Office in its Guidelines for Written Description, specifically in Example 16 (attached hereto as Appendix B), states "[c]onsidering the routine art-recognized method of making antibodies to fully characterized antigens, the well defined structural characteristics for

the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature, one of skill in the art would have recognized that the spectrum of antibodies which bind to antigen X were implicitly disclosed as a result of the isolation of antigen X." Thus, the disclosure of the well characterized antigen Tissue Factor and the disclosure of at least one antibody that binds tissue factor and inhibits binding of Factor X provides sufficient written description for claims directed to all antibodies having this property.

In addition, the specification describes the inhibition of TF activity by the H36.D2 antibody in a human bladder carcinoma cell line (see Example 7), and the detection of TF on the surface of human lung carcinoma and human melanoma tumor cells (see Example 11) using the chimeric cH36 antibody.

Because the instant specification provides a sufficient teaching to enable one of skill in the art to make a variety of antibodies that bind native human tissue factor to form a complex, whereby factor X binding to the complex is inhibited, and wherein the factor VII or VIIa binding to tissue factor is not inhibited and means to test the antibodies for anti-cancer activity, applicants request that this ground of rejection be withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 37, 38, 47, and 55-57 are rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite.

Specifically, the Examiner has rejected claim 37 as indefinite for insufficient antecedent basis for the term "the mammal." Applicants have amended claim 37 to recite proper antecedent basis for the term "the mammal." Reconsideration is respectfully requested.

The Examiner further rejected claim 37 as indefinite for recitation of the phrase "wherein the method further comprises contacting cancer cells expressing TF with the antibody or fragment to reduce the TF levels in the mammal to treat cancer." Applicants have amended claim 37 to remove this phrase. Reconsideration is respectfully requested.

Claims 38 and 55-57 were rejected as indefinite for insufficient antecedent basis for the term "the complex." Applicants have canceled claim 38 and have amended claim 37 to provide

proper antecedent basis for the term “the complex” in claims 55-57. Reconsideration is respectfully requested.

Claim 47 was rejected as indefinite for the recitation of “wherein the antibody comprises a sequence that has at least 70% sequence identity to SEQ ID NO:1.” Applicants have canceled claim 47 thereby rendering this rejection moot.

Rejection under 35 U.S.C. § 102

Claims 37, 38, 72, 51-61 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Edgington et al. (U.S. Patent No. 5,223, 427, the “‘427 patent”). The Examiner asserts that “the ‘427 patent teaches a method of treating a patient having tumor cells that express TF on their cell surface, such as carcinoma of breast and lung, by administering to the patient a[n] anti-TF monoclonal antibody (MoAb) or its immunologically active portions.” Applicants respectfully traverse the rejection.

“A claim is only anticipated if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” MPEP 2131. The ‘427 patent teaches an anti-TF antibody referred to as TF8-5G9 (“the 5G9 antibody”). The '427 patent does not teach or suggest a method of blocking factor X binding to tissue factor wherein tissue factor levels can be reduced in a mammal to treat cancer, as pointed out by the pending claims. Accordingly, this ground of rejection should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable consideration of the application is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at (617) 832-1738. If any fees are due, the Commissioner is hereby authorized to credit any overpayment or charge any deficiencies to Deposit Account No. **Deposit Account No. 06-1448, TNA-005.04.**

Respectfully submitted,
FOLEY HOAG

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Customer Number 25181

Patent Group
Foley Hoag LLP
155 Seaport Blvd.
Boston, MA 02210-2600
Tel: (617) 832-1738
FAX: (617) 832-7000



Charlene A. Stern-Dombal, Ph.D.
Reg. No. 57,961
Agent for Applicants